UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,627	04/29/2005	Peggy Wingard	006050.00067	2806

22907 7590 09/16/2008

BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
SUTTON, DARRYL C	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,627	WINGARD ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/21/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 05/21/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 12, 13 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Stella (US 6,204,257) in view of Lowrie.

The rejection is maintained.

Applicant argues that surprising and unexpected results concerning the potency of plasma propofol derived from the prodrug of formula I versus that derived from propofol itself have been demonstrated.

Examiner has analyzed the Examples disclosed by Applicant for a showing of the surprising and unexpected results. The Examples do not show the surprising or unexpected results argued by Applicant because they lack adequate experimental design. In Example 1, Applicant has only used a target controlled infusion, TCI, method to administer the drugs, and has only administered the disodium salt of formula I. In Example 2, Applicant has used a TCI method to administer the prodrug of formula I, and has only administered the disodium salt of formula I. In Example 3, Applicant has used bolus administration of the prodrugof formula I and a rapid infusion of propofol; has

produced conscious sedation with only 5 mg/kg and 10 mg/kg bolus injections of the prodrug of formula I; has only used the sodium salt of the prodrug of formula I.

After analyzing, even assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate with the scope of those showings. In Examples 1 and 2, Applicant has only used TCI to administer the drugs, not one parental bolus injection in an amount from about 2 mg/kg to less than 15 mg/kg; has only administered the disodium salt of formula I, i.e. Z^+ is an alkali metal ion not any alkali metal ion, a hydrogen or amine. In Example 3, Applicant has used a bolus dose to administer the prodrug of formula I, while administering propofol in a rapid infusion, not administered both compounds as a bolus dose; has produced conscious sedation with only 5 mg/kg and 10 mg/kg bolus injections of the prodrug of formula I, not with about 2 mg/kg to less than 15 mg/kg bolus injections; has only administered the disodium salt of formula I, i.e. Z^+ is an alkali metal ion, not any alkali metal ion, hydrogen or amine.

Applicant argues that nothing in Lowrie would have suggested that a conscious sedated state can be induced simply by administering a parental bolus injection of the propofol prodrug. The examiner would like to point out that the claim is drawn to a method “comprising” administration of a bolus injection of the prodrug. Therefore, the claim contemplates possible additional steps or active ingredients in the method. Therefore, the method of inducing sedation using a combination of a slow bolus injection of 1-2 mg/kg followed by a continuous infusion reads on the claim when it is given its broadest interpretation.

The applicant also argues that propofol dosages for inducing conscious sedation could not have been determined based on Lowrie's disclosure involving propofol; Lowrie provides no guidance as to what dosages or modes of administration of the prodrug would be effective for conscious sedation. The examiner disagrees. Lowrie teaches the use of a bolus injection of propofol, 1-2 mg/kg for producing sedation. As pointed out in the office action, "Sedation is a form of anesthesia that ranges from conscious sedation to a deep sedated state" (page 6, paragraph 4). Stella teaches the use of the prodrug for general anesthesia, but also points out that one skilled in the art of anesthesia will be able to ascertain an appropriate protocol for administering the compound. Stella teaches that the prodrug of propofol is cleaved in-vivo to propofol. It would reasonably be expected to produce sedation, i.e. anesthesia, ranging from conscious sedation to a deep sedated state, from a bolus injection whether one of ordinary skill in the art was aware of the increased potency of propofol derived from the prodrug of formula I or not. It would have been obvious to one of ordinary skill in the art that higher dosages, i.e. higher parenteral bolus injections, of sedating drugs cause higher levels of sedation. Optimization of the parenteral bolus dosages to produce the desired levels of sedation, i.e. from conscious to a deep sedated state, and to account for the compound being used in adults versus the children of Lowrie is also obvious to one of ordinary skill in the art.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is

(571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612